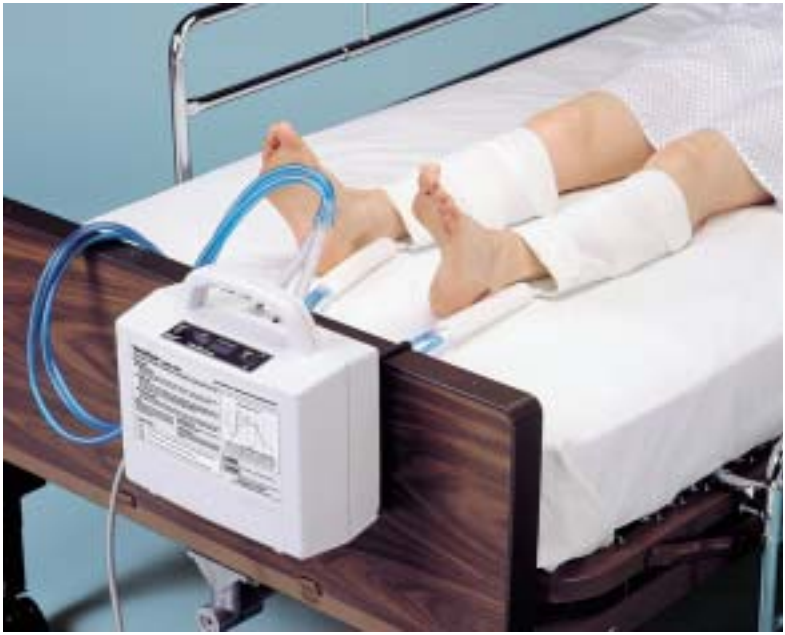
VenaFlow® system 30A, 30AXL, 30AXXL

Operator's Manual

prophylaxis for DVT and associated PE



VenaFlow system with Calf Cuff

AIRCAST® INCORPORATED

Contents

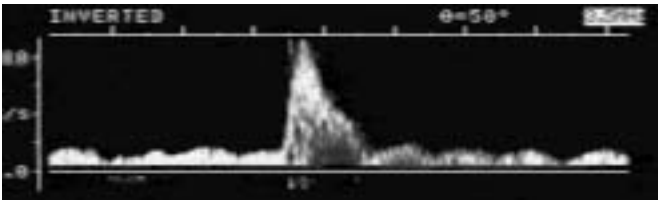
Introduction

Aircast® pioneered graduated, pneumatic compression for the functional management of orthopedic injuries. The VenaFlow system evolved from this unique experience, and from performance principles established by earlier researchers in pneumatic compression. VenaFlow provides intermittent pneumatic compression as a prophylaxis for deep vein thrombosis. This graduated, sequential, compression accelerates blood velocity and enhances fibrinolysis.[4,9,12,13]

Design Philosophy

The VenaFlow system is designed to move blood faster and be more comfortable than any other known device.

Studies show that the Aircast VenaFlow system increases venous velocity significantly more than other intermittent pneumatic compression (IPC) systems. This is because the compression is extremely rapid, graduated and sequential — principles for optimal DVT prophylaxis demonstrated by Kamm, et al, at MIT.[6,7,10] The patented Duplex™ aircell design, employed in the Calf and Foot Cuffs, reduces the risk of pooling of blood between compartments that is seen with conventional segmented cuffs.[13] In addition, the VenaFlow system's compression is asymmetric for more effective emptying of the veins. The unique cuffs are designed to enhance patient compliance and comfort, and are available in three designs (Calf, Foot, and Thigh) to suit individual physician preferences.



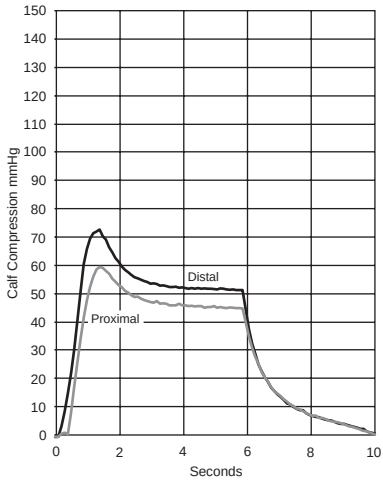
VenaFlow system's rapid, graduated compression causes a three to four fold increase in femoral vein velocity (Calf Cuff). In a typical Doppler trace, precompression velocity is .19 meters per second, the peak during compression, .92 m/s — an increase of 384%. This compares with the 80% to 140% increase found with conventional systems.[3,9]

Function

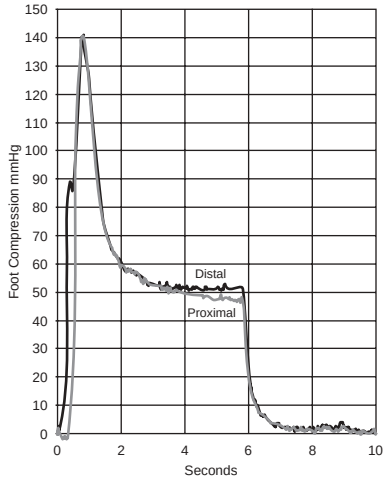
The cuffs are applied, pump and tube assembly connected, and pump turned on. Compression is rapid, graduated and sequential for maximum effectiveness. The distal aircell inflates rapidly, then settles to 52 mmHg ±10%, and the proximal aircell follows in .3 seconds to settle at 45 mmHg ±10%. After 6 seconds of compression, the cuffs deflate. This cycle repeats every minute.

When the pump is activated, the peak pressures gradually rise through the first five minutes of operation. This allows the patient to gradually adjust to the treatment.

Compression Curve Using Calf Cuff



Compression Curve Using Foot Cuff



The VenaFlow system pump automatically adjusts compression for each style of cuff. While peak pressures vary with each cuff style, the settle pressures remain consistent for all cuffs.

Indications

The N.I.H., Consensus Development Conference Panel on Prevention of Venous Thrombosis and Pulmonary Embolism (Volume 6, Number 2)[8] found that DVT is a marker for PE, and that risk of DVT is high following major high risk surgery: general, orthopedic, urological, neurological, gynecological, and trauma. The Panel found external pneumatic compression an effective and safe modality in these surgical categories.

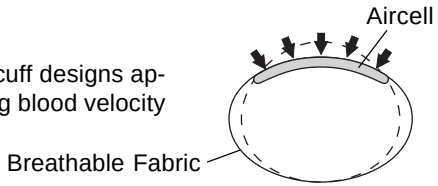
Contraindications

The VenaFlow system should not be used by persons with known or suspected deep vein thrombosis, congestive heart failure, pulmonary edema, thrombophlebitis, severe arteriosclerosis, or active infection. Do not use on extremities which are not sensitive to pain, where cuff will interfere with gangrene, on patients with vein ligation or recent skin grafts, or extreme deformity of the leg. Do not use the VenaFlow system where increased venous or lymphatic return is undesirable.

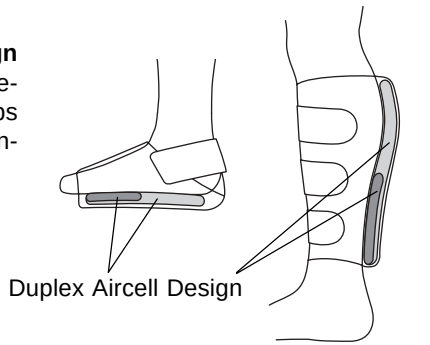
Cuff Features

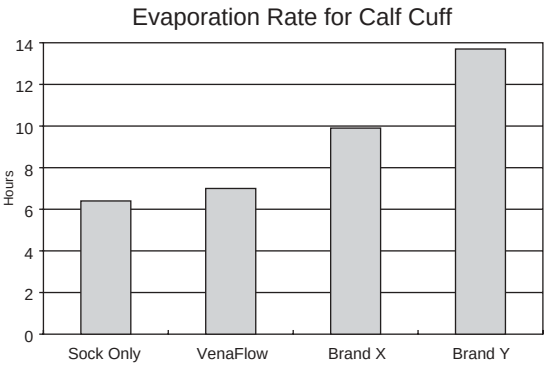
- **Comfort** All cuffs are made from lightweight, hypoallergenic fabric. This material is very breathable and encourages evaporation to keep the patient cool and comfortable. *(see Evaporation Rate Chart below)*.

- **Asymmetric Compression** All cuff designs apply focused pressure, maximizing blood velocity and total flow.



- **Seamless Duplex™ Aircell design** In both the Calf and Foot Cuff designs, the proximal aircell overlaps the distal, providing consistent, uninterrupted compression.

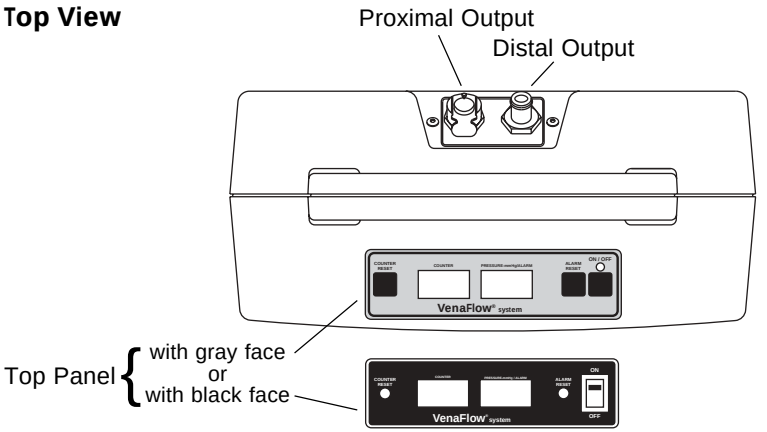




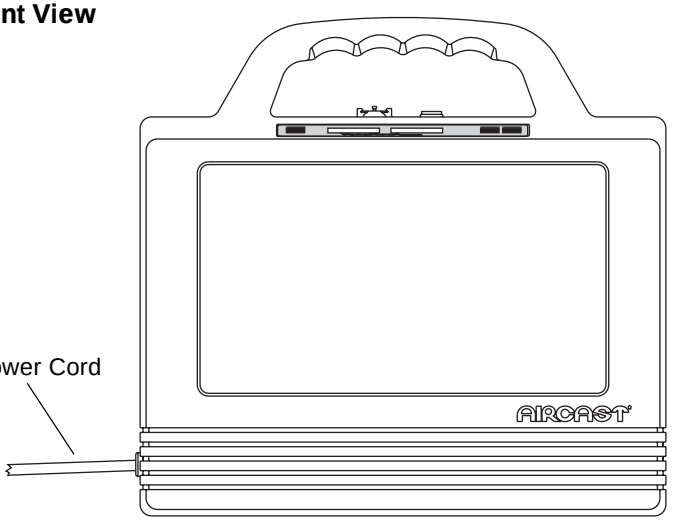
In tests to compare evaporation, a wet sock with 50 cc's of moisture was placed on an artificial leg. With nothing covering the sock, it took 6.4 hours to lose half its moisture. The test was repeated on each of the three products.

Pump Features

Top View



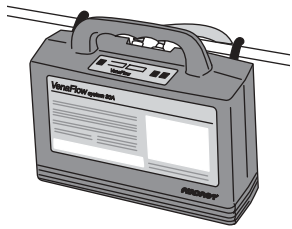
Front View



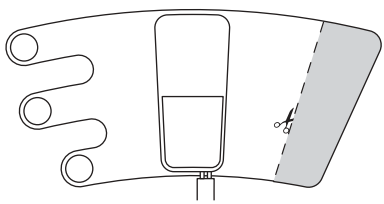
Application

❶ Prepare air pump and cuff(s)

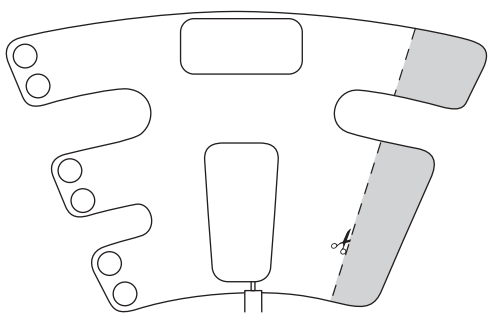
Hang pump from bed frame (foot of bed), bed rail, or rest on floor or table with handle facing upright. Connect power cord to a 115V AC — 60 Hz power source.



For patients with a small calf or thigh, trim Calf Cuff or Thigh Cuff as indicated.



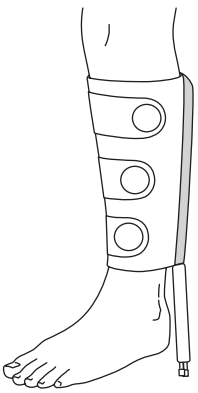
Trim Calf Cuff if necessary



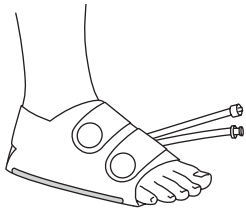
Trim Thigh Cuff if necessary

❷ Apply cuff(s)

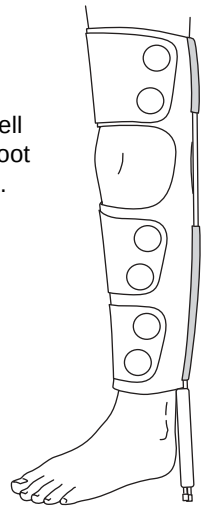
All cuffs are hypoallergenic and may be placed directly against the skin or over a light compression dressing.



Calf Cuff
Apply cuff with the aircell centered on back of leg and with tubes toward foot.



Foot Cuff
Apply cuff with the aircell centered on bottom of foot and with tubes on left.



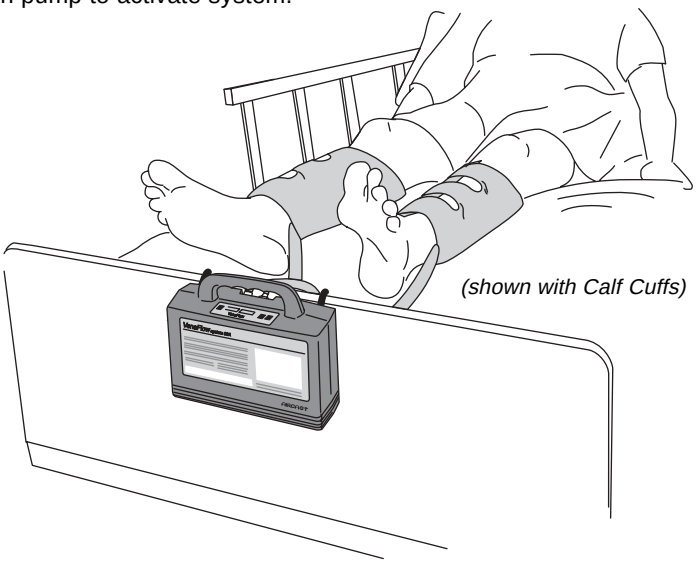
Thigh Cuff
Apply cuff with the aircells centered on back of calf and thigh and with tubes toward foot.

Be sure to secure cuff straps snug, but not tight. *A snug cuff delivers optimal performance.*

When using the Calf Cuff and Thigh Cuff, the position of the aircell on the calf and/or thigh does not significantly affect venous velocity, or the sequential performance of the system.

❸ Connect system

Attach the tube assembly to cuffs and pump.
Turn on pump to activate system.

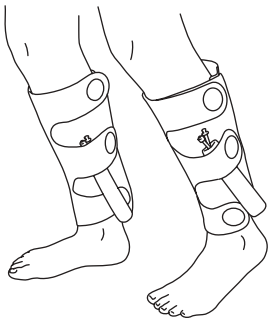


(shown with Calf Cuffs)

Be sure to check that all tube assembly connections are tight and cuffs are snug to achieve full pressure. Always turn off pump before readjusting or removing cuffs.

Ambulation

The Calf Cuff or Thigh Cuff may be worn while walking. Before ambulation, turn off pump. Disconnect tube assembly from each cuff and secure cuff tubes under lower strap.



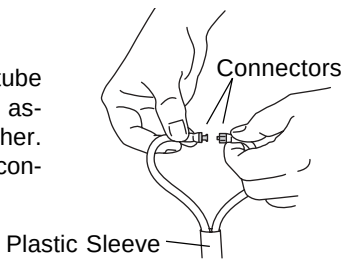
(shown with Calf Cuffs)

Single Cuff Application

The VenaFlow system pump functions normally when either one or two cuffs are applied.

Calf Cuff or Thigh Cuff

Apply single Calf or Thigh Cuff. Connect tube assembly to cuff. Secure free ends of tube assembly by firmly screwing connectors together. If necessary, slide plastic sleeve away from connectors to prevent tube obstruction.



(Calf or Thigh Cuff Only)

One Foot Cuff

Apply single Foot Cuff. Connect tube assembly to *both* the applied cuff and an unused Foot Cuff. (Both Foot Cuffs must be connected to the pump to achieve correct target pressures.)

Operation

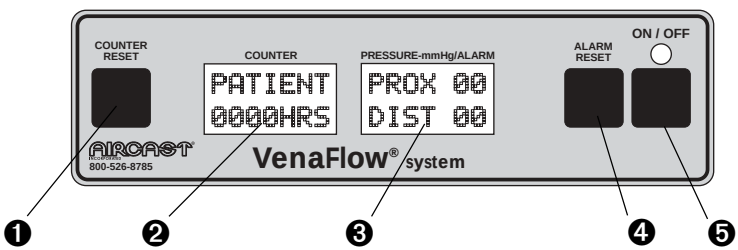
When the system is turned on, the pump is activated and begins to pressurize. When target pressure is achieved, the system begins a cycle and inflates the cuff aircells. The distal aircell inflates first with the proximal aircell inflating .3 seconds later. After 6 seconds of compression, the aircells deflate and the pressure display illuminates the distal and proximal pressures for fifty-four seconds. The pressure display is updated after every cycle. Pressure and inflate/deflate cycles are automatic and unit will activate an alarm if the system is not functioning properly *(see Top Panel Displays / Alarms)*.

Top Panel

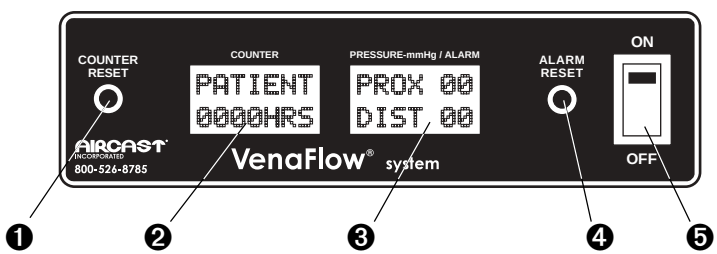
The Top Panel of the VenaFlow pump comes with either a gray or black face. The Top Panel functions the same whether the face is gray or black.

❶ **COUNTER RESET**	Resets counter back to zero.
❷ **COUNTER DISPLAY**	Displays length of time unit is in operation in addition to pressure alarms.
❸ **PRESSURE DISPLAY**	Displays settle distal and proximal pressures in addition to alarm instructions.
❹ **ALARM RESET**	Resets alarm after activation.
❺ **POWER SWITCH**	Sets power ON or OFF. Green light will illuminate when ON.

Top Panel with gray face



Top Panel with black face



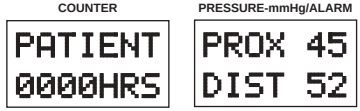
Top Panel Displays/Alarms

The counter and pressure displays, located on the top panel, illuminate patient hours and distal and proximal pressure. These displays also illuminate pressure alarms with alarm instructions. If proximal pressure is out of range, an alarm will sound and the counter display will indicate the type of alarm while the pressure display will provide instructions for correcting the pressure. In addition, the displays will illuminate when a tube is obstructed.

Alarms and Troubleshooting

Normal Operation:

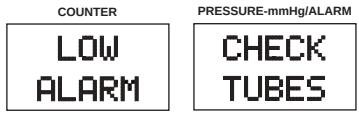
Distal pressure (52 mmHg ±10%) and proximal pressure (45 mmHg ±10%) are displayed and held until next cycle.



Note: During single cuff operation, the range between the proximal and distal pressures may be reduced. This is normal.

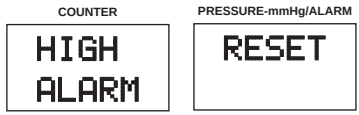
Low Pressure:

Alarm will activate. Check that all tube connections are tight and that cuffs are snug. Reset alarm.



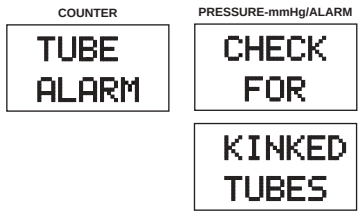
High Pressure:

Alarm will activate. Reset alarm. If alarm persists, return unit to Aircast®.



Obstructed Tube(s):

Alarm will activate. Check tube connections. Ensure that tubing is kink-free. If applicable, check that plastic sleeve is away from connectors *(see Single Cuff Application)*. Reset alarm.



If pressure remains out of range after resetting, replace the system and return the unit to Aircast. **Do not attempt to service.**

Service

In the event of a problem occurring with a VenaFlow system, return the unit, in the original container, to Aircast® for repair or replacement. Replacement shipping containers are available through Aircast Customer Service.

For orders or service, please contact Aircast Customer Service at:

Phone: (800) 526-8785 **Fax: (800) 457-4221**
Phone: (908) 273-6349 **Fax: (908) 273-1060**

or write:

Aircast Incorporated
92 River Road
P.O. Box 709
Summit NJ/USA 07902-0709

Warranty

Satisfaction – Aircast will provide prompt refund for any product that does not satisfy the physician for any reason whatsoever.

Durability – The Aircast VenaFlow system is covered by a 3 year unlimited warranty. Do not attempt to service the unit.

⚠ DANGER

Risk of explosion if used in the presence of flammable anesthetics.

⚠ CAUTION

Federal law restricts this device to sale by or on the order of a physician.

Pressure Verification

A Pressure Verification Kit (P/N 3004) is available for verification of indicated pressure.

Maintenance

All VenaFlow Disposable Cuffs (Calf, Foot, and Thigh) are supplied in individually sealed packages. They are for **single patient use only** and should be disposed of after each patient.

Cleaning

The tube assembly is reusable. Both the pump case and tube assembly can be cleaned with mild soap solution, antiseptic or disinfectant wipes. *Avoid excessive fluids over the top display.* Do not submerge. Do not attempt to open or service unit.

Optional Functional Test

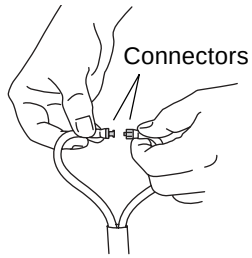
To obtain accurate readings, allow the pump to cycle for five minutes before beginning "Optional Functional Test" (peak pressures gradually rise through the first five cycles).

The Aircast VenaFlow system is maintenance-free. The "Optional Functional Test" is for *verification only, and not required before use.*

1. **Visual Test:**
   Inspect pump case, handle, hooks, connectors, and power cord for damage.

2. **Pressure Verification Test** (requires Pressure Verification Kit, P/N 3004)**:**
   Verify normal operation and correct pressure by following instructions included with the Aircast Pressure Verification Kit (P/N 3004).

3. **Alarm Verification Test:**
   Attach tube assembly to pump and connect power cord to 115V AC — 60 Hz power source. *Simulate* a kinked tube situation by firmly securing the male and female connectors together at *both* ends of the tube assembly. If only one end of the tube assembly is connected the kink alarm will not activate. Turn on pump to activate system.



   Under proper conditions, during the first cycle, the pressure display should indicate proximal and distal pressures greater than 40 mmHg. Due to the simulated "kink", the second cycle should activate an audible alarm with the display reading "TUBE ALARM", "CHECK FOR" "KINKED TUBES".

4. **Electrical Safety Test:**
   Perform electrical safety check in accordance with UL 2601 guidelines or your institution's standards.

If the unit fails any of these tests, return to Aircast for prompt repairs or replacement. **Do not attempt to service unit. If pump is removed from case, unit will be ungrounded.**

References

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14. Westrich GH, Sculco TP: Prophylaxis Against Deep Vein Thrombosis After Total Knee Arthroplasty. *J Bone Joint Surg 78-A(6):* 826–834, 1996

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Specifications

General

Size	11" × 11" × 5"
Weight	9 lbs
Power-Input	115V AC — 60 Hz
Cord Length	14 ft.
Mounting	Hook to bed foot board
Inflation Mode	Graduated/Sequential
Cuff Design	Asymmetrical
Indication	Prophylaxis for DVT
Pressure Range (preset)	Distal: 52 ±10% mmHg Proximal: 45 ±10% mmHg
Compression On	6 seconds
Pulse Frequency	1 per minute
Mode of Operation	Continuous Power

Environmental

Storage/Transportation Temperatures	-20°C to +70°C
Relative Humidity	10% – 90% Noncondensing
Altitude	0 to 3,048 m above sea level
Operating Temperatures	0°C to 50°C

Emissions/Immunity Specification

The VenaFlow system is compliant to EMC testing EN 60601-1-2, 1992.

UL and C-UL compliant to UL 2601 Standard for Medical and Dental Equipment.

Sizing

The VenaFlow Calf cuff is available in regular and extra-large sizes (both non-sterile and sterile). The VenaFlow Foot and Thigh Cuffs are one-size-fits-all. If necessary, the Calf and Thigh Cuff may be trimmed to accommodate a small calf or thigh *(see Application)*.

Components and Accessories

The VenaFlow system is available in three configurations: 30A, 30AXL, and 30AXXL.

P/N	Description
30A	VenaFlow system 30A *Includes:* Pump (3001), 5.5 ft. Tube Assembly (3007)
30AXL	VenaFlow system 30AXL *Includes:* Pump (3001), 8.5 ft. Tube Assembly (3007XL)
30AXXL	VenaFlow system 30AXXL *Includes:* Pump (3001), 10.5 ft. Tube Assembly (3007XXL)

Accessories:

P/N	Description	Qty
3010	VenaFlow Disposable Calf Cuff (u. o. m. is pair)	1
3011	Sterile VenaFlow Disposable Calf Cuff (u. o. m. each)	1
3012	VenaFlow XLarge Disp. Calf Cuff (u. o. m. is pair)	1
3014	Sterile VenaFlow XLarge Disp. Calf Cuff (u. o. m. each)	1
3015	VenaFlow Disposable Thigh Cuff (u. o. m. is pair)	1
3016	VenaFlow Disposable Foot Cuff (u. o. m. is pair)	1
3007	Tube Assembly (5.5 ft.)	1
3007XL	Extra Large Tube Assembly (8.5 ft.)	1
3007XXL	Extra Extra Large Tube Assembly (10.5 ft.)	1
3020	VenaFlow Operator's Manual	1
3004	Pressure Verification Kit	1

Latex

All components of the VenaFlow system are latex-free.

Ordering

For orders or service, please contact Aircast® Customer Service at:

Phone: (800) 526-8785 **Fax: (800) 457-4221**
Phone: (908) 273-6349 **Fax: (908) 273-1060**

or write:

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